

WHAT IS CLAIMED IS:

*See 31-36*

1. A septal defect closure device comprising first and second occluding disks, each disk comprising a flexible, biologically compatible membrane having a periphery and an elastically deformable frame carried about the periphery of the membrane, said frame being capable of being collapsed for passage through a catheter and elastically returning to a predetermined shape for tautly holding the membrane; a central portion of the membrane of the first disk being affixed to a central portion of the membrane of the second disk to define a central conjoint disk.
2. The closure device of claim 1 wherein the central conjoint disk is sized to be received within a septal defect.
3. The closure device of claim 2 wherein the central conjoint disk is sized to substantially fill the septal defect.
4. The closure device of claim 1 wherein the central conjoint disk is generally circular in shape.
5. The closure device of claim 1 wherein the central portions of the first and second membranes are sewn together to define the conjoint disk.
6. The closure device of claim 1 wherein the central portions of the first and second membranes are fixed to one another by a biologically compatible adhesive.
7. The closure device of claim 1 wherein the frame is formed of an elongate wire.

8. The closure device of claim 7 wherein the wire is formed of a superelastic material.
9. The closure device of claim 1 wherein the frame comprises a plurality of legs having opposed ends, one leg being flexibly connected to another leg at each end.
- 5 10. The closure device of claim 9 wherein the frame is integrally formed of a single wire.
11. The closure device of claim 10 wherein the wire is formed of a superelastic material.
- 10 12. The closure device of claim 10 wherein lengths of the wire define the legs, the wire being formed into a loop between adjacent ends of the legs to provide a flexible connection therebetween.
13. The closure device of claim 10 wherein lengths of the wire define the legs, at least one leg of the frame comprising two overlapping lengths of wire.
14. The closure device of claim 9 wherein the central conjoint disk has an axis, the legs being capable of being folded such that the ends of each of the legs of one of said first or second disks converge upon a point spaced axially outwardly of the conjoint disk.
- 15 15. The closure device of claim 14 wherein the point of convergence of the legs of the first disk are spaced distally of the conjoint disk and the point of convergence of the legs of the second disk are spaced proximally of the conjoint disk.

16. The closure device of claim 1 wherein the frame and disk are integrally formed from a sheet of superelastic material.

17. The closure device of claim 1, further comprising a tether for releasably attaching the closure device to a delivery means.

5 18. A method of closing a septal defect comprising the steps of:

(a) providing a closure device comprising first and second occluding disks, each disk comprising a flexible membrane having a periphery and an elastically deformable frame carried about the periphery of the membrane, a central portion of the membrane of the first disk being affixed to a central portion of the membrane of the second disk to define a central conjoint disk;

(b) collapsing the frames of the first and second disks and inserting the closure device in a catheter having a distal end;

(c) positioning the distal end of the catheter adjacent a septal defect;

(d) urging the first disk of the closure device out of the distal end of the catheter and permitting its frame to elastically return to a predetermined shape for holding its membrane tautly on a first side of the defect; and

(e) urging the second disk of the closure device out of the distal end of the catheter and permitting its frame to elastically return to a predetermined shape for holding its membrane tautly on a second side of the defect with the central conjoint disk being disposed within the defect.

19. The method of claim 18 further comprising the steps of determining the size of the septal defect and selecting a closure device having a conjoint disk sized to substantially fill the defect.

5        20. The method of claim 18 wherein the second disk is urged out of the distal end of the catheter by retracting the catheter in a proximal direction.

21. The method of claim 18 further comprising retracting the catheter in a proximal direction after the first disk has been urged out of the catheter until the first disk engages a septum.

10        22. The method of claim 18 wherein the frame of the closure device of the first disk includes a plurality of loops spaced along the length of the frame, the step of collapsing the frame of the first disk comprising the steps of passing a thread through at least two of said loops and drawing the thread substantially taut to collapse the frame.

15        23. The method of claim 18 wherein the closure device further comprises a tether attached thereto, further comprising the step of detaching the tether from a delivery means after urging the second disk out of the catheter.

24. The method of claim 18 further comprising the steps of  
a) providing a delivery means having an elongate urging member for urging the closure device through the catheter and a control means for selectively, accurately advancing the urging member;

- b) urging the closure device through the catheter with the urging member to a position adjacent the distal end of the catheter; and
- c) manually manipulating the control means to advance the urging member sufficiently to urge the first disk out of the catheter without urging the second disk out of the catheter.

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25. The method of claim 24 wherein the closure device includes a tether, the delivery means being capable of releasably securing the tether, further comprising the step of releasing the tether from the delivery means after urging the second disk out of the catheter.

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26. The closure device of claim 1 further comprising an elastically deformable central frame carried about the conjoint disk.

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27. A system for closing septal defects comprising a closure device and delivery means for deploying the closure device to occlude a septal defect; the closure device comprising first and second occluding disks, each disk comprising a flexible, biologically compatible membrane having a periphery and an elastically deformable frame carried about the periphery of the membrane, said frame being capable of being collapsed for passage through a catheter and elastically returning to a predetermined shape for tautly holding the membrane, a central portion of the membrane of the first disk being affixed to a central portion of the membrane of the second disk to define a central conjoint disk; the delivery means comprising an elongate urging member for urging the closure device

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through a catheter and a remotely located control means for selectively, accurately advancing the urging member.

28. The system of claim 27 wherein the closure device further comprises a tether, the delivery means including means for releasably holding said tether.

5 29. The system of claim 28 wherein said holding means comprises an elongate wire for holding the tether and lever means for retracting the wire to release the tether.

10 30. A delivery system for delivering and deploying a septal defect closure device through a vascular system, comprising an elongate, flexible urging member for urging the closure device through a catheter and a remotely located control means for selectively, accurately advancing the urging member, the control means comprising an externally threaded, generally tubular shaft connected to said urging member and a manually rotatable rotor mounted thereon, the rotor being internally threaded to mate with the threads on the shaft such that by rotating the rotor through a known angle the shaft may be advanced a known distance, advancing the urging member substantially the same 15 distance.